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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,174	01/14/2004	Willi Kaiser	31-HL-5510(5024-00126)	4195
26753	7590	09/11/2006	EXAMINER	
ANDRUS, SCEALES, STARKE & SAWALL, LLP 100 EAST WISCONSIN AVENUE, SUITE 1100 MILWAUKEE, WI 53202			OROPEZA, FRANCES P	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/757,174	KAISER ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/23/06(Response) and 5/30/06(Amendment).
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,7,9-15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,9-15 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>6/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response

1. The Applicant amended at least the independent claims in the response filed 6/23/06 hence, the rejection of record is withdrawn and a new rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 103

2. Claims 1-4, 6, 9-14 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) in view of DeLuca et al. (US 6238338) and further in view of Wang (US 5967994), known hence as Wang ('994).

Rohde teaches the monitoring of electrocardiograms using a portable modular diagnostic medical device comprising an electrocardiogram (ECG) cartridge (12) with an input terminal and leads, an instrument amplifier (62), an analog to digital converter (72), memory, and a screen (20). Waveforms from individual leads can be viewed on the screen, and the output of the signal via the serial port permits the ECG signal to be sent via cable to a computer, the computer inherently having peripherals such as a printer and memory, the memory read as external memory. The functionality of the monitoring device can be expanded or potentially expanded, such as adding the detection of cyclic artifacts and the selection of a lead based on the lack of artifacts (abstract; col. 3 @ 1-7, 18-22; col. 4 @ 21-23, 38-55; col. 5 @ 5-11, 18-20, 35-37, 57-61; col. 5 @ 66 – col. 6 @ 14; col. 6 @ 43-47; col. 7 @ 30-38, 55-60; col. 8 @ 33-46; col. 9 @ 29-46; col. 13 @ 7-9, 20-32; col. 16 @ 31-37).

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As discussed in the previous paragraph of this action, Rohde discloses the claimed invention except for the analog-to-digital converter being connected between the instrument amplifier and the analysis module.

DeLuca et al. teach bio-signal monitoring using a component arrangement of the analog-to-digital converter (57) being connected between the instrument amplifier (55) and the analysis module (58) for the purpose of processing the electrocardiogram signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the analog-to-digital converter being connected between the instrument amplifier and the analysis module in the Rohde system in order to process the input signal such that the processing results in a larger dynamic signal range important in sampling low level bio-signals contaminated with large artifacts, and to minimize the need to auto-scale the gain (fig. 5; col. 3 @ 11-18, 31-38, 59-62; col. 4 @ 65 – col. 5 @ 2; col. 5 @ 48-53, 58-63).

As discussed in the previous three paragraphs, modified Rohde discloses the claimed invention except for a twelve lead ECG system (claims 6, 14, 23) and an analysis module including a processor and software to detect cyclic artifact and select a lead for analysis based on the lack of cyclic artifact (claims 1, 9, 17).

Wang ('994) teaches signal characterization using a twelve lead ECG system and an analysis module, including a processor and software, to detect cyclic artifact and to select a lead for analysis based on the lack of cyclic artifact for the purpose providing the optimum lead configuration for an ECG study and for the purpose of determining the signal quality of the lead(s) sensing the ECG signal. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a twelve lead ECG system and to have used an

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analysis module, including a processor and software, to detect cyclic artifact and to select a lead for analysis based on the lack of cyclic artifact in the modified Rohde system in order to provide a high quality, comprehensive ECG signal that, based on analysis, will have minimal distortion enabling the physician to make an accurate diagnosis (fig. 6,9; col. 1 @ 8-15; col. 2 @ 40-56; col. 3 @ 37 – col. 4 @ 11; col. 4 @ 19-34, 48-57; col. 5 @ 3-17; col. 6 @ 29-36; col. 13 @ 21-25; col. 16 @ 4-16).

The Applicant's arguments filed 6/23/06 have been fully considered, but they are not convincing.

The Applicant asserts Rohde does not teach expanding the functionality of the medical device to include functionality such as the detection of cyclic artifacts and the selection of a lead based on the lack of artifacts. The Examiner disagrees. Rohde teaches expanding the functionality of the medical device (col. 3 @ 1-7, 18-22; col. 4 @ 21-23; col. 16 @ 32-37) to include functionality such as the detection of cyclic artifacts and the selection of a lead based on the lack of artifacts, read to be a different diagnostic medical functionality. The specific teaching of an analysis module including a processor and software to detect cyclic artifacts and to select a lead based on the lack of artifacts is taught by Wang (US 5967994) as noted in the rejection of record. The specific teaching of an analog-to-digital converter being connected between the instrument amplifier and the analysis module is taught by DeLuca et al. (US 6238338) as noted in the rejection of record.

In response to the Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the reasons stated in the rejection of record for combining the references are taken from the references themselves, the reason for the combination being noted and cited in the rejection of record. These reasons to combine these references have been reviewed and are deemed appropriate.

In response to the Applicant's argument that the examiner has combined an excessive number of references, reliance on three or four references in a rejection does not weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

In response to the Applicant's argument that the age of the cited references indicates a lack of some teaching or suggestion supporting the combination. The Examiner disagrees. The Examiner finds the combination of references in the rejection of record teaches all the claim limitations. The reasons stated in the rejection of record for combining the references are taken from the references themselves, the reason for combination being noted and cited in the rejection of record. These reasons to combine these references have been reviewed and are deemed appropriate.

Based on the rejection of record and the discussion above, the claims stand rejected.

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3. Claims 7, 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rohde (US 5876351) and DeLuca et al. (US 6238338) and Wang (US 5967994), known hence as Wang ('994), and further in view of Wang (US 6119035), hence known as Wang ('035). As discussed in paragraph 2 of this action, modified Rohde discloses the claimed invention except for the multi-lead electrocardiogram (ECG) with five (claims 15, 24) or seven leads (claim 7).

Wang ('035) teaches synthesizing an ECG using a multi-lead ECG comprising five leads or seven leads for the purpose of synthesizing a twelve lead electrocardiogram. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the multi-lead ECG comprising five leads or seven leads in the modified Rohde system in order to quickly and easily produce a user acceptable synthesized twelve lead ECG, the result of the synthesis being easily check by adding one or more other leads, the synthesized twelve lead ECG reducing the number of leads required for the ECG, hence avoiding the accurate preparation and placement of ten electrodes require for the twelve lead ECG, and reducing the significant clutter that arises from the wires and connects associated with each electrode (abstract; col. 3 @ 12-30; col. 4 @ 47-51; col. 6 @ 12-36, 44-53; col. 7 @ 15-31).

Claim Objection

4. In claim 1, line 3, it appears "e" should be --the--.

Statutory Basis

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Conclusion

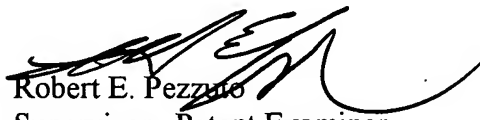
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3766

FPO
8/29/06


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766